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| ART UNIT 1885 | PAPER NUMBER |
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DATE MAILED: 12/22/97

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/915,004

Applicant(s)
Goto et al.

Examiner
Robert Schwartzman

Group Art Unit
1805



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-31 is/are pending in the application.

Of the above, claim(s) 7-9, 15, 17, 18, 20, 21, 23, 24, and 26-31 is/are withdrawn from consideration.

☒ Claim(s) 6, 16, 19, 22, and 25 is/are allowed.

☒ Claim(s) 1-5 and 10-14 is/are rejected.

☒ Claim(s) 1 and 12 is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☒ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Claims 1-31 are pending in this application.

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-6, 10-14, 16, 19, 22 and 25, drawn to a protein, classified in class 530, subclass 350.
- II. Claims 7-9, 15, 17, 18, 20, 21, 23, 24 and 26, drawn to a cDNA, classified in class 536, subclass 23.1.
- III. Claims 27-31, drawn to an antibody, classified in class 530, subclass 387.1.

The inventions are distinct, each from the other because of the following reasons: Groups I-III are drawn to distinct products having different chemical structures and different uses and are not disclosed as capable of use together.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Paula A. Campbell on December 2, 1997 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-6, 10-14, 16, 19, 22 and 25. Affirmation of this election must be made by applicant in responding to this Office action. Claims 7-9, 15, 17, 18, 20, 21, 23, 24 and 26-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

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Priority

Acknowledgment is made of applicant's claim for benefit under 35 U.S.C. 120 to international application PCT/JP96/00374 filed February 20, 1996 and foreign priority based on applications filed in Japan on February 20, 1995 and July 21, 1995. It is noted, however, that applicant has not filed certified copies of these applications as required by 35 U.S.C. 119(b) and 365(c).

Drawings

Since allowable subject matter has been indicated, applicant is encouraged to submit formal drawings in response to this Office action. The early submission of formal drawings will permit the Office to review the drawings for acceptability and to resolve any informalities remaining therein before the application is passed to issue. This will avoid possible delays in the issue process.

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Specification

The abstract of the disclosure is objected to because it contains more than one paragraph. Correction is required. See MPEP § 608.01(b).

This application contains sequence disclosures (page 23, Figures 9-12) that are not properly identified by sequence identifier numbers. Correction is required.

The specification is objected to as the Brief Description of the Drawings should properly follow the Summary of the Invention. Correction is required.

Claim Objections

Claims 1 and 12 are objected to because of the following informalities: the claims are not formatted as a single sentence as step (c) recites "inhibition activity: inhibits..... It is suggested that the phrase "inhibition activity:" be deleted.

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Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 4 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the osteoclastogenesis inhibitory factor protein of claim 1, does not reasonably provide enablement for any osteoclastogenesis inhibitory factor protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Claim 4 is drawn to a method of producing an osteoclastogenesis inhibitory factor protein by cultivating human fibroblasts, forming a lysate and separating the factor using ion-exchange, affinity and reverse phase chromatography. The specification discloses a specific factor purified from human fibroblasts which has osteoclastogenesis inhibiting activity and four variants of this protein, all of which can be purified by the claimed method. However, no evidence is provided that other types of osteoclastogenesis inhibitory proteins exist in human fibroblasts are that such other proteins could be produced by the claimed method. In the absence of any guidance or evidence, one of skill in the art could not determine if other inhibitory factors exist and could be

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purified as claimed without undue experimentation. Thus, the claim should be limited to a method of producing the protein disclosed in the specification.

Claims 1-3 and 10-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite as it does not indicate in step (c) what is being heated. It is suggested that the claim be amended to recite "heating said protein". Additionally, the phrase "substantially in accordance" in step (d) is indefinite as there is no clear definition in the specification of what is meant by "substantially".

Claim 2 is vague and indefinite as it refers to the single amino acid sequence of SEQ ID NO: 7 but recites "sequences".

Claim 10 is vague and indefinite as it is not clear if the protein is expressed from one cDNA or many cDNAs. It is suggested that the claim be amended to recite "a cDNA".

Claim 11 is vague and indefinite as the recitation of percent identity is indefinite when the specification does not disclose how the calculation is made. Since there are numerous methods of

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determining identity between two sequences, particularly when it comes to gaps and other significant differences, disclosure of specific algorithms and parameters to be used is necessary to adequately define sequences meeting the claimed limitation.

Claim 12 is vague and indefinite as it does not indicate in step (c) what is being heated. It is suggested that the claim be amended to recite "heating said protein". Additionally, step (d) is indefinite as it recites "an internal amino acid sequence" but refers to three sequences.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 4 and 5 are rejected under 35 U.S.C. 102(a) as being anticipated by Tsuda et al.

Tsuda et al. teaches (entire document) an osteoclastogenesis inhibitory factor protein purified from human fibroblasts cultured on alumina ceramic pieces. The protein was purified by ion-exchange, affinity and reverse phase chromatography.

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Conclusion

Claims 1-5 and 10-14 are rejected. Claims 1 and 12 are objected to. Claims 6, 16, 19, 22 and 25 are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Schwartzman whose telephone number is (703) 308-7307. The examiner can normally be reached on Monday through Friday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, George Elliott, can be reached at (703) 308-4003. The fax number for this group is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)-308-0196.



**NANCY DEGEN
PRIMARY EXAMINER**

Robert A. Schwartzman, Ph.D.
December 18, 1997